



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/626,585 | 07/25/2003 | Poonsook Keelapang | ThaiBiotec004 | 9541 |

7590 11/21/2008
Ms. Nuttina Netsuwan
113 Thailand Science Park, Paholyothin Rd.
Klong Luang, 12120
THAILAND

| |
|----------|
| EXAMINER |
|----------|

CHEN, STACY BROWN

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1648

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

11/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/626,585 | Applicant(s) KEELAPANG ET AL. | |
| | Examiner Stacy B. Chen | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

I. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. The specification is objected to because the sequences on page 7 must be identified by SEQ ID NO. Correction is required.

Claims Summary

3. The claims are drawn to a recombinant genetic construct and virus comprising a full-length genome of a dengue virus that has been modified (relative to a wild-type dengue virus) at a 13-amino acid encoding region just proximal to the prM cleavage site. The region is devoid of negatively-charged amino acids and contains additional positively-charged amino acids relative to a wild-type dengue virus. (The claims refer to a prototype dengue virus, but it is not clear what the prototype is. The Office will interpret the prototype to be a wild-type, as in claim 3.) The virus having this modification has less prM protein on its viral envelope because of an enhanced internal cleavage of the prM protein (due to the modification of amino acids described above). The virus induces infected C6/36 mosquito cells to fuse at a neutral pH to a greater

Art Unit: 1648

extent than a wild-type dengue virus and is exported out of the cells to a lesser extent, result in a lower virus titer in the culture medium.

Although not claimed, Applicant has construct one virus having these characteristics, MBU 01-2002, which contains SEQ ID NO: 1. SEQ ID NO: 1 is a novel DNA sequence that encodes the modified portion of the prM region referred to in the claims. The claims are not limited to that sequence, but it is an example of such a sequence.

Claim Objections

4. Claims 1-6 are objected to for the following informalities:
 - Claims 1-6 recite improper grammar with regard to the use of the term "amino acid" being plural/singular.
 - Claims 4-6 should be amended to recite more traditional language. For example in claim 4, more appropriate language is, "A mutant dengue virus of claim 3 *which* contains less prM protein" [emphasis added].
 - A claim may only contain one sentence; however claim 5 has two sentences.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are not clear with regard to the reference to "the prototype dengue

Art Unit: 1648

virus” or “the wild type dengue virus”. There is no standard prototype dengue virus mentioned early in claim 1 to provide antecedent basis for the latter recited “the prototype dengue virus”.

Similarly, there is no mention of “the wild type dengue virus” in claim 3, also lacking antecedent basis. Recitation of “a wild type dengue virus” would be acceptable. With regard to a prototype dengue virus, this term is not sufficiently defined in the specification aside from an example of a prototype being dengue virus strain 16681 (see page 9, second full paragraph for example).

Correction is required.

Conclusion

6. No claim is allowed. The prior art does not teach or fairly suggest the claimed genetic construct or virus comprising the genetic construct as claimed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648